IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: ABBOTT LABORATORIES, ET AL., PRETERM INFANT NUTRITION PRODUCTS LIABILITY LITIGATION	**MDL No. 3026** **Master Docket No. 1:22-cv-00071** **Hon. Rebecca R. Pallmeyer** **JURY DEMAND**
This Document Relates to: **ALL CASES**	

DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION
TO EXCLUDE PLAINTIFFS' EXPERT DR. LOGAN SPECTOR

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Plaintiffs' defense of Dr. Spector depends on evading the facts around his work to avoid any form of gatekeeping. They claim that it does not matter that Dr. Spector deviated from the care he would apply in his academic work and that he did not know whether he would claim more than a "possibility" of causation outside court. They claim it does not matter that he purported to conduct a ***systematic*** literature review but missed more studies than he found. And they claim it does not matter that every factor of his purported Bradford Hill analysis was either unsupported or simply missing, so much so that Plaintiffs are forced to try justifying it with arguments and materials that he neither invoked nor considered. But "[u]nsubstantiated attorney argument … is no substitute for competent, substantiated expert testimony," and Plaintiffs cannot rely on lawyer argument to meet their admissibility burden under Rule 702.[1]

Plaintiffs' evasion is most extreme as to Defendants' most foundational methodological challenge. Dr. Spector conceded that causation depends on addressing alternative explanations for data, and yet he could not rule out the alternative explanation for the NEC data that the scientific community has embraced—that human milk is uniquely protective against NEC, and formula does not cause it. Lacking any response to this core methodological defect, Plaintiffs simply ignore it.

Plaintiffs also ignore Dr. Spector's concessions on fit and qualifications. Their fit arguments disregard his admission that he could not give an opinion in a case involving babies fed anything less than 100% formula. This means that he cannot offer an opinion in any bellwether case, as none of those infants had a 100% formula diet. And Plaintiffs' qualifications arguments disregard Dr. Spector's concessions about his lack of prior work with NEC or formula and his failure to educate himself through his work in this case.

[1] *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1068 (Fed. Cir. 2005).

Rule 702, including as amended,[2] exists to preclude experts like Dr. Spector. "[A]ny step that renders the analysis unreliable … renders the expert's testimony inadmissible." *Cage v. City of Chicago*, 979 F.Supp.2d 787, 808 (N.D. Ill. 2013). Dr. Spector's analysis fails at every step.

I. Dr. Spector's Methodology is Not Reliable

A. Dr. Spector Admits That He Used a Different Method and Offered a Different Conclusion in Court than He Would Use or Offer out of Court.

Plaintiffs do not dispute that experts must follow the "same standards of intellectual rigor that are demanded in their professional work." *Cummins v. Lyle Indus.*, 93 F.3d 362, 369 (7th Cir. 1996); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). Dr. Spector fails this requirement: he admitted he would have applied far more rigor to his work had he conducted it outside court. *See, e.g.*, Ex. 7 at 201:6–19, 202:8–14. And he justified his in-court deviations by suggesting that it was permissible to follow different rules in court, which is precisely what Rule 702 precludes. *Id.* at 372:14–20 ("This was for a court audience that does not – is not concerned with the same things as a general scientific audience ….").

Without precedent, Dr. Spector then went further and admitted that his courtroom work differed so much from his academic work that he could not say that he would reach a causation opinion outside of court. Mot. at 9–10. Plaintiffs' only answer to this remarkable concession—buried in a single paragraph on the last page of their brief—is to suggest that this in-court/out-of-court chasm is just semantics: experts calibrate their language depending on whether they are testifying or publishing. Opp. at 22.[3] While that suggestion might be debatable for Dr. Spector's

[2] Plaintiffs rely largely on pre-amendment cases, and they address the amended rule only by misleadingly quoting from a single paragraph in the Advisory Committee notes. Opp. at 9.

[3] Plaintiffs cite an article stating that "[m]any medical journals… restrict the use of causal language to the reporting of randomized clinical trials." Opp. at 22. But "randomized clinical trials" are the studies upon which Dr. Spector purports to base his opinions.

testimony that he would not use the phrase "reasonable degree of scientific certainty" outside court, Ex. 7 at 198:6–14, it does nothing to overcome his specific admissions that (1) he would state any non-litigation opinions "in terms of probability," *id.* at 200:20–201:1; (2) he has no idea what probability he would assign because "I haven't thought of it until this moment," *id.* at 201:3–5; (3) he does not know if he "would state anything stronger than there is a *possibility* that preterm formula causes NEC"—"I don't know," *id.* at 201:6–14; and (4) he could not do this because he has not undertaken the "hours and hours of deliberation" and "agoniz[ing] over every word" that would, in his own telling, be necessary to reach such a view outside court, *id.* at 201:6–19. These deficiencies alone require his exclusion.

B. Dr. Spector's Systematic Literature Review Missed More Studies Than It Found.

Plaintiffs offer two primary responses to the fact that Dr. Spector's systematic literature review methodology failed its most basic requirement of being "systematic." ***First***, they suggest that his incredibly wide-ranging results (which varied between suggesting formula was associated with a 9% reduction in NEC to more than a 1600% increase in NEC, *see* Ex. 21 at 15–16) are admissible because they landed close enough to the results of published analyses, Opp. at 11–13. But this "close enough" argument misses the point of Rule 702, which is about methodology rather than results. A methodology cannot be defended under Rule 702 on the grounds that, in Plaintiffs' view, it came close enough to the "right result."[4] Opp. at 11; *see Gopalratnam v. Hewlett-Packard*

[4] Plaintiffs cannot use Cochrane publications to bolster Dr. Spector: Dr. Spector refused to endorse Cochrane and "skimmed" these studies only ***after*** he reached his opinions, Ex. 7 at 266:7–12, 231:6–17, 252:19–25; he missed multiple studies included in the Cochrane analyses, *id.* at 246:1–14, and his results materially varied from Cochrane, with one result being more than ***2.5 times*** higher than what the Cochrane publications found, *compare* Opp. at 12 (citing Cochrane risk ratios of 1.84 and 1.87) *with* Opp. at 17 (citing Spector risk ratio of 4.62).

Co., 877 F.3d 771, 781 (7th Cir. 2017) ("The focus, [of a Rule 702 analysis] must be solely on principles and methodology.") (internal quotation marks and citation omitted).

Second, Plaintiffs misstate the degree of error in Dr. Spector's work. In their telling, he missed only one study and that was below an "acceptable" rate of 13%. Opp. at 13–14 (citing a study Dr. Spector relied on that concluded a 13% error rate was too high). This argument ignores the facts of Dr. Spector's shifting analyses. Mot. at 6–8. After attempting to defend the fact that he found only twelve randomized trials prior to his first deposition, Dr. Spector added thirteen studies to his analyses after that deposition. Ex. 21 at 7–8. He then claimed that he relied on the results of those new analyses in reaching his opinions, Ex. 20 at 23:2–4, and then was shown to have still missed three further studies, Ex. 20 at 107:21–108:1. Stated differently, he ***missed*** more studies (16) than he found (12). This is a staggering error rate that exceeds by many factors even what Plaintiffs concede is unacceptable. *See* Rule 702, Advisory Comm. Notes (citing error rate as relevant factor in Rule 702 analysis); *Hartman v. Ebsco Indus.*, 758 F.3d 810, 817 (7th Cir. 2014) ("An expert's methodology can be evaluated by considering its error rate[.]").

Plaintiffs' only defense to this remarkable error rate is to claim that these missed studies do not matter because Dr. Spector adopted a defective search strategy that caused him to miss them, Opp. at 13, even though he admitted he would have included a large number of them had he actually read them, *e.g.*, Ex. 20 at 152:22–153:3. But justifying admittedly missed relevant studies by invoking an erroneous review strategy that was "designed to identify relevant studies," Opp. at 10, only confirms that he used a defective and unreliable methodology.

C. Dr. Spector Failed to Adequately Consider the Bradford Hill Factors.

Merely listing the Bradford Hill criteria and claiming that an expert followed them is not enough to survive Rule 702 review. *In re Paraquat Prods. Liab. Litig.*, 730 F.Supp.3d 793, 840–41 (S.D. Ill. 2024); *In re Onglyza (Saxagliptin) & Kombiglyze (Saxagliptin & Metformin) Prods.*

Liab. Litig., 93 F.4th 339 (6th Cir. 2024); *In re Acetaminophen – ASD-ADHD Prods. Liab. Litig.*, 707 F.Supp.3d 309, 337 (S.D.N.Y. 2023). But that is the essence of Plaintiffs' Bradford Hill defense, which fails to address Defendants' actual challenges.

Specifically, Plaintiffs do nothing to rebut Defendants' showing that for two-thirds of the factors Dr. Spector either conducted no meaningful analysis of his own or admitted the factor was not met. Mot. at 12–13. This alone warrants exclusion. *See In re Acetaminophen*, 707 F.Supp.3d at 337 ("[D]istrict courts must ensure that '[t]he specific way an expert conducts [a Bradford Hill] analysis is reliable.'") (internal quotation marks omitted); *In re Nexium Esomeprazole*, 662 Fed. App'x 528, 530 (9th Cir. 2016) (excluding expert who "[a]t best, … analyzed three of the nine Bradford Hill factors"). Plaintiffs similarly offer no response to the fact that, for fully one-third of the factors, Dr. Spector relied on Dr. Sucre despite conceding that he would not do so had he actually understood her lack of credentials, Mot. at 12, and he otherwise relied on his "common sense," which alone requires his exclusion. *See Trexler v. City of Belvidere*, 2023 WL 415184, at *5 (N.D. Ill. Jan. 25, 2023) ("Opinion testimony based on common sense is unhelpful to a jury and is inadmissible."); *Equal Employment Opportunity Comm'n v. SkyWest Airlines, Inc.*, 2024 WL 4530127, at *2 (N.D. Tex. Oct. 18, 2024) (similar). Finally, Plaintiffs highlight the inadequacy of Dr. Spector's Bradford Hill analysis by offering claims about the science and sources to support his testimony that he affirmatively rejected. [5]

[5] For example, Plaintiffs attempt to shore up Dr. Spector's failure to meaningfully evaluate dose response, Ex. 7 at 301:16–25, in a way that only highlights his unreliability. Plaintiffs invoke the Meinzen-Derr study, Opp. at 20, but Dr. Spector read it only ***after*** giving his opinions and then dismissed it as "***completely inappropriate*** to informing the question before me," Ex. 7 at 298:9–17, 299:21–25 (emphasis added). And Plaintiffs' invocation of the Cochrane analyses, Opp. at 16, runs headlong into Dr. Spector's failure to review them and his criticism of one for using what he called "inappropriately causal" language when it concluded, consistent with the scientific consensus, that human milk "reduces" the risk of NEC. Ex. 7 at 244:1–8.

D. Dr. Spector Failed to Consider the Alternative Explanation for the Data That the Entire Medical Community Accepts.

Dr. Spector agreed with the foundational scientific principle that, to move from a statistically significant finding to a causation opinion, a scientist must consider (and rule out) alternative explanations for the finding. Here, the medical community has settled on a consensus explanation for the finding of different NEC rates between human milk and formula: human milk protects against NEC. *E.g.*, Ex. 1; Mot. at 15–16. The studies that Dr. Spector purports to rely on repeatedly make that point, *see* Ex. 7 at 74:6–10, as does the Consensus Statement that the nation's leading health agencies recently issued.[6] Dr. Spector himself proved how strong this consensus about an alternative explanation for the data was: he was unable to identify anyone not paid to give a causation opinion who in fact concluded causation. *See* Ex. 7 at 133:21–23, as amended by Ex. 25 line 6.

Lacking any response to this core defect, Plaintiffs simply ignore it: they do not contest the medical consensus that human milk protects against NEC; and they do not challenge Dr. Spector's failure to address this alternative explanation. Nor could they. When asked about the known protective effect of human milk, even Dr. Spector admitted that he "believe[s] that's a reasonable supposition." Ex. 7 at 65:14–20. But he admitted that, while he "saw some language" discussing human milk's protective effect, he took no steps to "quantitate it." Ex. 7 at 74:6–10.

[6] Reflecting how they are unable to argue around this consensus, Plaintiffs ask the Court to accept their insinuation that Defendants somehow coopted the FDA, the CDC, and the NIH, simply because one of those agencies, which regulates Defendants' products, met with Defendants and had concerns about the impact of the litigation on public health. This insinuation provides no basis at all for ignoring these agencies' Consensus Statement or for falsely claiming that Defendants "bought and paid" for it. Opp. at 14. In any event the articles Dr. Spector relied on establish this consensus, as does Dr. Spector's inability to identify a single non-retained scientist who supports his views.

Dr. Spector's admission that he stands alone in his explanation of the data is a striking "red flag" of unreliability that calls for his exclusion. *In re Paraquat Prods. Liab. Litig.*, 730 F.Supp.3d at 850; *see also, e.g.*, *Chapman v. Maytag Corp.*, 297 F.3d 682, 688 (7th Cir. 2002) (excluding testimony that was "novel and unsupported by any article, text, study, scientific literature or scientific data produced by others in his field"); *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 677 (6th Cir. 2010) ("[W]hat science treats as a useful but untested hypothesis the law should generally treat as inadmissible speculation."); *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F.Supp.3d 1075, 1234 (S.D. Fla. 2022) ("[N]o independent scientist or governmental body has made the analytical leap from the existing data as [Plaintiffs' expert] does, and the Court deems this fact to be evidence of an unreliable methodology."). Dr. Spector's admitted failure to consider what the medical consensus accepts as the alternative non-causal explanation for this data, which even he admits is "reasonable" is fatal for his opinions. Ex. 7 at 65:14–20; *see, e.g.*, *Gopalratnam*, 877 F.3d at 787; *Liebhart v. SPX Corp.*, 917 F.3d 952, 963 (7th Cir. 2019) (affirming exclusion of expert who did not "adequately account for obvious alternative explanations."). That Plaintiffs do not even attempt to defend this defect only confirms this point.

II. Dr. Spector Conceded That His Opinions Do Not Fit with These Cases.

Plaintiffs describe Defendants' attack on the "fit" of Dr. Spector's opinions as a "fiction." Opp. at 7, 21. Far from being a "fiction," Defendants' argument is based on what Dr. Spector himself clearly and unequivocally ***volunteered***. He would say that formula is causative only when babies are fed 100% formula: "When you get to 100 percent [formula], I'll say it's sufficient." Ex. 7 at 287:6–7; Mot. at 20–24.

Plaintiffs argue "[t]here is no requirement an expert identify the precise number of milliliters an infant must consume to trigger NEC." Opp. at 19. But that argument misconstrues the nature of Defendants' challenge to Dr. Spector. Defendants are not arguing that Dr. Spector

should be excluded because he did not identify the exact to-the-milliliter amount of formula required to cause NEC. They seek his exclusion because (1) he expressly agreed that "causation depend[s] on the percentage of the diet that is made up of formula," Ex. 7 at 286:19–22, and (2) he admittedly could not offer the opinion that even a 99% formula diet was sufficient to cause NEC, *id.* at 287:9 ("Not able to give you that number."). Defendants are not aware of ***any*** case in this MDL that fits Dr. Spector's self-described 100% formula criteria. The Court has a "rigorous gatekeeping function to ensure that … the expert's testimony is sufficiently tied to the facts of the case, so that it fit[s] the dispute and will assist the trier of fact." *Cohen v. Cohen*, 125 F.4th 454, 460 (3d Cir. 2025) (internal citations and quotation marks omitted); *see also Deimer v. Cincinnati Sub-Zero Prods., Inc.*, 58 F.3d 341, 345 (7th Cir. 1995) (citing *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 591 (1993)). Dr. Spector's testimony is untethered to the facts of any of these cases.

Similarly, Plaintiffs suggest that, because Dr. Spector is not a specific cause expert, the disconnect between his opinions and the facts of these cases does not matter. But as Plaintiffs themselves otherwise concede, "whether an expert's approach lines up with the basic facts of the case goes to the relevance and admissibility of the testimony itself." Pls.' Rule 702 Mot., ECF 612, at 12 (quoting *Owens v. Auxilium Pharms., Inc.*, 895 F.3d 971, 973 (7th Cir. 2018)). Dr. Spector's "hypothetical" patient who received only 100% formula bears no relation to the facts of any identified case. *Id.* (quoting *Owens*). His opinions thus are inadmissible.

To overcome these admissions about the limits of his opinions, Plaintiffs note that the studies on which Dr. Spector relies included varying amounts of formula from "small[] amounts" to "an exclusive formula diet." Opp. at 20. But this is irrelevant because Dr. Spector ***himself*** did not reach a causation opinion on anything less than an exclusive-formula diet. Instead, he testified that (1) his opinion was limited to diets comprising "100 percent" formula Ex. 7 at 287:6–7; and

(2) he did not do any analysis to offer a different opinion. Ex. 7 at 254:6–8 ("Q. Did you do any analysis of formula limited to formula as a supplement to maternal milk? A. I did not."). The Rule 702 question is not what an attorney might say in a brief, but what the ***expert*** offers as their causation opinion and what work they did to reach that opinion. *See Invitrogen Corp.*, 429 F.3d at 1068 ("Unsubstantiated attorney argument … is no substitute for competent, substantiated expert testimony.").

Nor is Dr. Spector's self-imposed limitation surprising. It is fully consistent with his testimony that outside of court, he does not know if he would offer a causation opinion stronger than a mere "possibility." Ex. 7 at 201:6–14. And even for his litigation-only opinion, he didn't do the work to offer a causation opinion for less than 100% formula, admitting that that he "did not" conduct "***any analysis*** of formula limited to formula as a supplement to maternal milk" or focus on NEC risk for "infants based on the percentage of formula they were fed." Ex. 7 at 254:6–8, 393:17–20. For cases like *Etienne* (<10% formula) and *Mar* (about 5% formula), he similarly stated he would ***not*** "offer an opinion" that there's even an "increase [in] the risk of NEC"—much less causation—when an infant gets only a "10 percent bovine product supplement." *Id.* at 359:10–16. ***Plaintiffs ignore all of this.***

Plaintiffs take a similar approach for infants born above 1,500 grams, claiming that "[t]he studies he evaluated typically included infants <1,500 grams and/***or* <37** weeks gestational age." Opp. at 21 (emphasis in original). But, again, the question is what ***Dr. Spector*** offered for his causation opinion, not what attorneys say in briefs. And Dr. Spector could not have been clearer. He explained that while some the studies "may have included" infants over 1,500 grams, "none of the studies focused on such infants." Ex. 7 at 155:4–18. As a result, he did not know the "relative risk" for infants above 1,500 grams" and, in fact, did not know if there would be ***any*** "increase in

NEC rates with preterm formula versus infants with a birth weight of above 1,500 grams." *Id.* at 155:4–18, 108:10–14. He believed that "[t]here is a degree of extrapolation one can make" beyond the studies' focus, but he "***did not do that analysis***." *Id.* at 394:19–395:11. Thus, for instance, Dr. Spector made no effort to extrapolate to infants above 1,500 grams and certainly did not address infants like the one in *Diggs* born above 2,000 grams, admitting that he did not "have any data that really addresses that." *Id.* at 345:14–24.

III. Dr. Spector Is Not Qualified

Plaintiffs fail to show that Dr. Spector has any experience with NEC or preterm nutrition, beyond his half-hearted attempt to claim expertise because he once cited an article with the word "NEC" in its title ten years ago. Ex. 7 at 310:19–25. Instead, they say that it is enough that he is an expert in some area within "pediatric epidemiology." Opp. at 10. Under this argument, any epidemiologist who studied *any* pediatric issue—for example, allergies in children—would be qualified to testify on any pediatric issue they chose, from adolescent mental health, to factors impacting school performance, to Dr. Spector's claimed expertise in "the causes of childhood cancer." Logan Spector, Univ. of Minn., https://perma.cc/LW95-X78V. Such a permissive standard would negate Rule 702's requirement that the expert's "specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue." Fed R. Evid. 702(a). The case law rejects this argument, and the Court should too. *See Gayton v. McCoy*, 593 F.3d 610, 617 (7th Cir. 2010) (relevant question is not whether expert "is qualified in general, but whether his qualifications provide a foundation for him to answer [the] specific question").

CONCLUSION

For all these reasons, the Court should exclude Dr. Spector's testimony.

Dated: March 21, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document was served upon counsel of record on March 21, 2025, via the Court's electronic filing system and via email for any material provisionally filed under seal.

/s/ Emily S. Ullman